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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/335,022 06/17/99 JOHANNSEN

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EXAMINER

QAZI, S

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

05/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/335,022

Applicant(s)

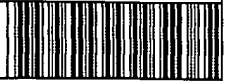
Monica Johannsen

Examiner

Sabiha Qazi-

Group Art Unit

1616



☒ Responsive to communication(s) filed on Mar 20, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Final Office Action on Merits

Invention: The instant invention is drawn to process of isolation of vitamin D from an isomeric mixture which comprises carrying out the separation by column chromatography using supercritical or liquid carbon dioxide.

Status of the Application

Claims 1-8 are pending.

Claims 7 and 8 are added.

Claims 1-8 are rejected.

All claims are examined.

No claim is allowed.

Applicant's response filed in paper no. 5, dated 3/20/00 is hereby acknowledged. Amendments are entered.

Rejection MAINTAINED

Claims 1-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (CA 113:198104, abstract of Zhongguo Yiyao Gongye Zazhi (1990), 21(6), 256-61) in view of Lee et al. (CA 124:105153, abstract of J. Microcolumn Sep. (1995), 7(5), 477-83) for the same reasons set forth in office action mailed in paper no. 2, dated 9/14/99.

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The instant invention is drawn to process of isolation of vitamin D from an isomeric mixture which comprises carrying out the separation by column chromatography using supercritical or liquid carbon dioxide.

Zhang et al. teaches the separation of 6 isomers separated by using irradiation technique and the purification on silica column (stationary phase).

Instant claims differ from the reference in claiming the liquid CO₂ for separation by column chromatography using liquid CO₂.

Lee et al. alleviates this deficiency by teaching the separation of coal tar vitamins and other related compounds. The enhance fluidity liquid mobile phase containing CO₂/methanol/water are used in a column.

These references are combinable because they are from the same field of endeavor.

It would have been obvious to one skilled in the art to combine the teachings of prior art supra to separate the vitamin D derivatives particularly when Zhang et al. teaches irradiation technique and the purification on silica column (stationary

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phase) and Lee et al. Teaches the use of liquid CO₂ for separation.

One skilled in the art would find ample motivation from the prior art to separate vitamin D derivatives as instantly claimed for the reasons cited above.

Nothing unobvious to separate the vitamin D as instantly claimed by the process known in the art, unless any unexpected results are seen.

The determination to employ the size and shape of the silica gel particles (claim 4) and use as stationary phase in claim 3 and would have been within the skills of the one familiar with the art.

Response to Arguments

Applicant's response has been fully considered but is not found persuasive. Following reasons apply.

1. The basis of arguments is that the instant invention is not obvious because prior art uses reverse phase HPLC whereas instant invention uses normal phase HPLC. Furthermore, applicant argue that with respect to claims requiring the use of supercritical CO₂, the Examiner has not met the burden.
2. Examiner disagree with the arguments because Examiner has already established a prima facie case. Examiner would like to

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draw the attention of applicants in that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re appreciate* 12 USPO d. 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPO 12 (CCA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPO 569 (CCA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPO 685, 688; *In re Best*, 195 USPO 430 and *In re Marosi*, 218 USPO 289, 293.

The cited case are not relevant to the instant case and does not appropriately apply.

Applicants argue about the size and shape of Silica gel. Examiner understands that one who is familiar with the separation techniques such as HPLC and column chromatography would know what type of silica or solvent should be used for better separation depending on the nature of the component in the mixture to be separated or purified.

One skilled in the art would know what type HPLC should be used for a particular separation i.e. reverse phase HPLC or normal phase HPLC. There are various types of column for HPLC are

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available in the market in different sizes for analytical or preparatory purposes having different types of resins or solid phases.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Each reference cited in 892 teaches the use of liquid carbon dioxide or super critical carbon dioxide for the purification, separation or extraction of the compounds.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

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*date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.*

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

4/29/00


Sabiha N. Qazi Ph.D.

Examiner, Art unit 1616